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**APPLICATION NUMBER: 10/795,843**

**FILING DATE: *March 08, 2004***

**RELATED PCT APPLICATION NUMBER: *PCT/US05/06745***



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13146 U.S. PTO

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UTILITY  
PATENT APPLICATION  
TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	0803-0111
First Inventor	Dilip K. Nakhasi
Title	Structured Lipid Containing Compositions ...
Express Mail Label No.	EV322849415US

22390 U.S. PTO  
10/795843

030804

## APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

## ADDRESS TO:

Mail Stop Patent Application  
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1. ☒ Fee Transmittal Form (e.g., PTO/SB/17)  
(Submit an original and a duplicate for fee processing)
2. ☐ Applicant claims small entity status.  
See 37 CFR 1.27.
3. ☒ Specification [Total Pages 47]  
(preferred arrangement set forth below)
  - Descriptive title of the invention
  - Cross Reference to Related Applications
  - Statement Regarding Fed sponsored R & D
  - Reference to sequence listing, a table, or a computer program listing appendix
  - Background of the Invention
  - Brief Summary of the Invention
  - Brief Description of the Drawings (if filed)
  - Detailed Description
  - Claim(s)
  - Abstract of the Disclosure
4. ☐ Drawing(s) (35 U.S.C. 113) [Total Sheets       ]
5. Oath or Declaration [Total Sheets 2]
  - a. ☒ Newly executed (original or copy)
  - b. ☐ Copy from a prior application (37 CFR 1.63(d))  
(for continuation/divisional with Box 18 completed)
  - i. ☐ DELETION OF INVENTOR(S)  
Signed statement attached deleting inventor(s)  
name in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).
6. ☐ Application Data Sheet. See 37 CFR 1.76

7. ☐ CD-ROM or CD-R in duplicate, large table or Computer Program (Appendix)
8. Nucleotide and/or Amino Acid Sequence Submission  
(if applicable, all necessary)
  - a. ☐ Computer Readable Form (CRF)

## b. Specification Sequence Listing on:

- i. ☐ CD-ROM or CD-R (2 copies); or
- ii. ☐ Paper

c. ☐ Statements verifying identity of above copies

## ACCOMPANYING APPLICATION PARTS

9. ☐ Assignment Papers (cover sheet & document(s))
10. ☐ 37 CFR 3.73(b) Statement of Power of Attorney  
(when there is an assignee)
11. ☐ English Translation Document (if applicable)
12. ☐ Information Disclosure Statement (IDS)/PTO-1449 Citations
13. ☐ Preliminary Amendment
14. ☒ Return Receipt Postcard (MPEP 503)  
(Should be specifically itemized)
15. ☐ Certified Copy of Priority Document(s)  
(if foreign priority is claimed)
16. ☐ Nonpublication Request under 35 U.S.C. 122  
(b)(2)(B)(i). Applicant must attach form PTO/SB/35 or its equivalent.
17. ☒ Other: Certificate of Express Mailing.....

18. If a CONTINUING APPLICATION, check appropriate box, and supply the requisite information below and in the first sentence of the specification following the title, or in an Application Data Sheet under 37 CFR 1.76:

☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No.: .....

Prior application information:

Examiner .....

Art Unit: .....

For CONTINUATION OR DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 5b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

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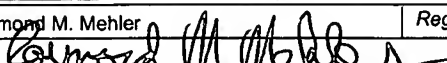
Name (Print/Type)

Raymond M. Mehler

Registration No. (Attorney/Agent)

26,306

Signature



Date

03/08/2004

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# FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$ ) 1360

## Complete if Known

Application Number  
Filing Date March 8, 2004  
First Named Inventor Dilip K. Nakhasi  
Examiner Name  
Art Unit  
Attorney Docket No. 0803-0111

## METHOD OF PAYMENT (check all that apply)

☒ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

☒ Deposit Account:

Deposit Account Number 50-1039  
Deposit Account Name Cook, Alex, McFarron, etc

The Director is authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☐ Credit any overpayments

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## FEE CALCULATION

### 1. BASIC FILING FEE

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description	Fee Paid
1001 770	2001 385	Utility filing fee	770
1002 340	2002 170	Design filing fee	
1003 530	2003 265	Plant filing fee	
1004 770	2004 385	Reissue filing fee	
1005 160	2005 80	Provisional filing fee	
SUBTOTAL (1)			(\$ ) 770

### 2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims	Extra Claims	Fee from below	Fee Paid
48	-20** = 28	18	504
Independent Claims 4	-3** = 1	86	86
Multiple Dependent			

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description
1202 18	2202 9	Claims in excess of 20
1201 86	2201 43	Independent claims in excess of 3
1203 290	2203 145	Multiple dependent claim, if not paid
1204 86	2204 43	** Reissue independent claims over original patent
1205 18	2205 9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) (\$ ) 590

\*\*or number previously paid, if greater; For Reissues, see above

## FEE CALCULATION (continued)

### 3. ADDITIONAL FEES

Large Entity Small Entity

Fee Code (\$)	Fee Code (\$)	Fee Description	Fee Paid
1051 130	2051 65	Surcharge - late filing fee or oath	
1052 50	2052 25	Surcharge - late provisional filing fee or cover sheet	
1053 130	1053 130	Non-English specification	
1812 2,520	1812 2,520	For filing a request for ex parte reexamination	
1804 920*	1804 920*	Requesting publication of SIR prior to Examiner action	
1805 1,840*	1805 1,840*	Requesting publication of SIR after Examiner action	
1251 110	2251 55	Extension for reply within first month	
1252 420	2252 210	Extension for reply within second month	
1253 950	2253 475	Extension for reply within third month	
1254 1,480	2254 740	Extension for reply within fourth month	
1255 2,010	2255 1,005	Extension for reply within fifth month	
1401 330	2401 165	Notice of Appeal	
1402 330	2402 165	Filing a brief in support of an appeal	
1403 290	2403 145	Request for oral hearing	
1451 1,510	1451 1,510	Petition to institute a public use proceeding	
1452 110	2452 55	Petition to revive - unavoidable	
1453 1,330	2453 665	Petition to revive - unintentional	
1501 1,330	2501 665	Utility issue fee (or reissue)	
1502 480	2502 240	Design issue fee	
1503 640	2503 320	Plant issue fee	
1460 130	1460 130	Petitions to the Commissioner	
1807 50	1807 50	Processing fee under 37 CFR 1.17(q)	
1806 180	1806 180	Submission of Information Disclosure Stmt	
8021 40	8021 40	Recording each patent assignment per property (times number of properties)	
1809 770	2809 385	Filing a submission after final rejection (37 CFR 1.129(a))	
1810 770	2810 385	For each additional invention to be examined (37 CFR 1.129(b))	
1801 770	2801 385	Request for Continued Examination (RCE)	
1802 900	1802 900	Request for expedited examination of a design application	

Other fee (specify)

\*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$ )

## SUBMITTED BY

Name (Print/Type) Raymond M. Mehler Registration No. 26,306 Telephone 312-236-8500  
Signature [Signature] Date 03-08-2004

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PATENT  
Attorney Docket 0803-0111

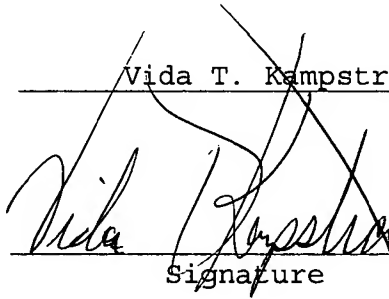
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03/08/2004

Date

STRUCTURED LIPID CONTAINING COMPOSITIONS AND METHODS WITH  
HEALTH AND NUTRITION PROMOTING CHARACTERISTICS

Description

Background of the Invention

Field of the Invention

[001] This invention generally relates to compositions of structured lipids and phytosterol esters. These compositions are especially suitable for use as components having health and nutrition promotion characteristics. More particularly, the invention relates to structured lipids for use as edible oils in combination with phytosterol esters in a variety of applications for promoting health and nutrition enhancement for those applications, such as in products for consumption and/or use by living beings, especially humans.

Description of Related Art

[002] Vegetable-based edible oil compositions long have been used in baking, frying and food dressing applications. Edible oil products provide taste, nutrition and anti-stick properties for any number of pan cooking, baking, dressing or similar types of uses and applications. Edible oil products of this general type include liquid oils, cooking oils, margarines, whipped spreads, tub margarines, shortenings, oils, sprayable compositions, salad dressings and the like. Edible oils also can be included in compositions administered to individuals in compositions that are not necessarily mainstream food products. Some can be directed to fine tuning

nutritional input or addressing metabolism objectives.

Traditional edible oil products, including those of the long chain variety, have been used in these types of applications.

[003] In the health, nutrition and metabolism art, publications suggest the usefulness of phytosterols in oil-based compositions. References which are in this general field include St-Onge, et al., "Consumption of a Functional Oil Rich in Phytosterols and Medium-Chain Triglyceride Oil Improves Plasma Lipid Profiles In Men," *American Society for Nutritional Sciences*, 0022-3166/03, (2003), *Journal of Nutrition*, Volume 133, pages 1815-1820, (2003) reports a study evaluating the effects of a combination of medium chain triglyceride oil, phytosterols and flaxseed oil on plasma lipid concentrations and LDL particle size. Another article discussing plant sterols or phytosterols is St-Onge, et al., "Phytosterols and Human Lipid Metabolism: Efficacy, Safety and Novel Foods," *Lipids*, Volume 38, No. 4, pages 367-375, (April, 2003). This article reports on studies regarding cholesterol-lowering efficacy of plant sterols with a view toward greater use of phytosterols in heart health promotion.

[004] Medium chain triglyceride (MCT) edible oils are known in the art including Seiden U.S. Patent No. 5,288,512, Bertoli et al. U.S. Patent No. 5,395,629, Hidaka U.S. Patent No. 5,503,855 Takeuchi U.S. Patent Publication No. 2002/0001660, and Heydinger and Nakhasi, "Medium Chain Triacylglycerols, *Journal of Food Lipids*, Volume 3, pages 251-257 (1996). Additional articles concerning MCT art include the following. St-Onge, et al., "Medium-Chain Triglycerides Increase Energy Expenditure and Decrease Adiposity in Overweight Men," *Obesity Research*, Volume 11, No. 3, (March, 2003) indicates that upper body adipose tissue in this study decreased using a functional oil blend of medium chain triglyceride oil, canola oil, flaxseed oil, coconut oil, and unesterified stanol/sterol mixture. St-Onge et al., "Greater

Rise in Fat Oxidation With Medium Chain Triglyceride Consumption Relative to Long Chain Triglyceride is Associated With Lower Initial Body Weight and Greater Loss of Subcutaneous Adipose Tissue," *International Journal of Obesity*, Volume 27, Pages 95-102 (2003) reports on a study to the effect that body weight decreased with medium chain triglyceride consumption when compared with long chain triglyceride consumption. These references, and each of the publications and patents noted throughout herein, are incorporated by reference hereinto.

[005] Publications such as these define these medium chain triglyceride or medium chain triacylglycerol (MCT) compounds as being a class of lipids of glycerol ester fatty acids. MCTs are esters of glycerol with medium chain fatty acids of 6 to 12 carbon chain lengths. Sources typically are lauric oils. Coconut and palm kernel oils contain significant quantities of C8 (caprylic) and C10 (capric) chains. Often, isolated fractions of C8 and C10 acids contain small amounts of C6 and C12 acids as well. Generally, MCT esters are saturated. Accordingly, the primary components of MCT edible oils have C8:0 and C10:0 fatty acid chains.

[006] References of Forbes Medi-Tech Inc also discuss phytosterol compositions. Stewart et al. U.S. Patent No. 6,087,353 describes phytosterol compositions which are esterified and subsequently hydrogenated. These are said to be suitable for use alone or for incorporation into foods, beverages, pharmaceuticals, nutraceuticals, and the like. Zerawistowski et al., International Publication No. WO 01/91587 describes oil compositions comprising short, medium and long chain triglycerides and the use thereof in reducing weight gain. Zawistowski et al., also discusses phytosterols, which incorporates phytostanols as noted therein. These phytochemicals are presently believed to have an ability to decrease serum cholesterol levels when fed to a number of



mammalian species, including humans. Zawistowski et al. indicates that the relationship between cholesterol and phytosterol is apparently due in part to similarities in the respective cholesterol and phytosterol chemical structures. The mechanism set forth in references such as these is that phytosterols displace cholesterol from the micellar phase to reduce its absorption or compete with cholesterol in its absorption process. Esterification of triglycerides is generally referenced in Zawistowski et al., including referring to interesterifying short, medium and long chain triglycerides for forming described chain residues.

**[007]** Interesterification is a known reaction of triacylglycerol structures whereby individual fatty acid structures at positions of the triglyceride being interesterified are interchanged on the glycerol moiety. This is at times referred to or recognized as a randomization wherein fatty acid moieties from one glycerol component of a triacylglycerol are exchanged with those of a glycerol component of another triacylglycerol. This results in triacylglycerol structures which have interchanged fatty acid moieties that vary from glycerol structure to glycerol structure. Art in this area includes Pelloso et al. U.S. Patent No. 5,434,278, Doucet U.S. Patent No. 5,908,655, Cherwin et al. U.S. Patent No. 6,124,486 and Liu et al. U.S. Patent No. 6,238,926.

**[008]** The art of interesterification has developed to form, for example, triglyceride compositions which provide certain melt profiles that can be of interest in certain applications. Generally these are recognized herein as "structured lipids" in order to help distinguish the interesterified products from other products which are physical blends of the same components but that have not been subjected to interesterification.

[0009] Heretofore, it has not been appreciated that the combination of interesterification technology and MCT technology and phytosterol technology would be especially advantageously applied to the task of improving health, nutrition and metabolism promoting compositions having a substantial edible oil content. An especially important problem in this regard, which is addressed by interesterified components according to the invention, is to provide a composition that has health, nutrition and improved metabolism promoting characteristics while simultaneously exhibiting very acceptable properties for combining with and/or adding into products for ingestion by and/or treatment of individuals. Most especially, it has been found that the compositions of this invention are substantially equal, or improved, substitutes for conventional edible oils used in making and/or formulating food products.

#### Summary of the Invention

[0010] In accordance with the present invention, products are provided which can be used in place of, or in combination with, conventional edible oil products such as domestic oils or tropical oils. These products are compositions of specially constructed edible oils in combination with a phytosterol ester component. These products have as a principal component a structured lipid which is a product of the interesterification of an edible domestic oil triglyceride and a medium chain triglyceride. These structured lipids are combined with phytosterol esters into so-called healthy oil compositions. When desired, these compositions can be formulated with components of a type typically included within compositions for a selected intended use.

[0011] The structured lipid and phytosterol compositions have the ability to function well in food systems, especially for baking, sautéing, stir-frying and as an oil component of a

... ..

... ..

dressing or other product that is used and/or stored at room temperature or refrigerated temperatures. By virtue of this good functionality of these compositions, the health, nutritional and positive metabolic benefits of phytosterols and of medium chain triacylglycerols are provided in traditional products which are likely to be more readily consumed by those who can benefit from the health attributes of the components.

[0012] A general aspect or object of the present invention is to provide compositions which combine structured lipids with phytosterol esters to provide compositions suitable for health and nutrition promotion in individuals.

[0013] An aspect or object of the present invention is that it provides medium chain triglycerides which have been modified by longer chain edible oils, for the purpose of enhancing health and/or nutrition of products within which they are combined together with phytosterol esters, including when compared with compositions having blends of the same MCT and longer chain components that are not subjected to interesterification.

[0014] Another aspect or object of this invention is that it provides structured lipids displaying a solids fat content which is substantially liquid at 10°C, and is very suitable for combining with phytosterol esters into compositions which can be liquid and clear at room temperature and below.

[0015] Another aspect or object of the present invention is providing a process for accomplishing randomized interesterification of medium chain edible oils with long chain edible oils and the use of the resulting product in compositions for health and/or nutrition promotion in a form which facilitates consumption for reaping the benefits of the composition in humans or other mammals.

[0016] Another aspect or object of this invention is that it provides an improved composition and method which combines

the virtues of MCT technology and phytosterol technology with the special improvement of interesterification for enhancing compatibility and shelf stability of compositions which exhibit excellent suitability for use in food products and preparations.

[0017] Other aspects, objects and advantageous of the present invention will be understood from the following description according to the preferred embodiments of the present invention, specifically including stated and unstated combinations of the various features which are described herein.

#### Description of the Preferred Embodiments

[0018] As required, detailed embodiments of the present invention are disclosed herein; however, it is to be understood that the disclosed embodiments are merely exemplary of the invention, which may be embodied in various forms. Therefore, specific details disclosed herein are not to be interpreted as limiting, but merely as a basis for the claims and as a representative basis for teaching one skilled in the art to variously employ the present invention in virtually any appropriate manner.

[0019] The present invention is directed toward structured lipids produced from medium chain triglycerides. Medium chain triglycerides usually are produced commercially by splitting and distilling fatty acids from coconut or palm kernel oils. Production includes esterification with glycerine to form a triglyceride having fatty acid chain lengths of from C6 to C12. These known edible oils typically contain 50 to 80 weight percent of C8 caprylic fatty acids and between about 20 and about 50 weight percent of C10 capric fatty acids. Minor levels, typically between about 1 and about 2 weight percent, of either or both of C6 caproic fatty acids and C12 lauric fatty acids can be present in some such products.

[0020] Known medium chain triglyceride, or "MCT," products include some NEOBEE® products such as NEOBEE® M-5 (trademark and product of Stepan Company), Aldo MCT (trademark and product of Lonza Inc.), CAPTEX® 300 (trademark and product of Abitec Corp.), and MIGLYOL® 812 (trademark and product of Clionova, Inc.). Traul et al., "Review Of The Toxicologic Properties Of Medium-Chain Triglyceride", *Food and Chemical Toxicology*, 38, pages 79-98 (2000) indicate that MCTs are essentially non-toxic in acute toxicity tests conducted in several species of animals. This article also indicates that MCTs exhibit virtually no ocular or dermal irritant potential, even with prolonged eye or skin exposure. This article also indicates that MCTs exhibit no capacity for hypersensitivity induction. According to this publication, the safety of MCTs in human dietary consumption has been indicated up to levels of 1 gram per kilogram of body weight.

[0021] Another publication indicates that MCTs result in lower fat deposition when compared with long chain triglycerides. This is noted in Ingale et al., "Dietary Energy Value of Medium-Chain Triglycerides", *Journal of Food Science*, Volume 64, No. 6, pages 960-963 (1999). Conclusions reached in this article state that differences in energy utilization show that increments of heat associated with the metabolism of MCTs appears to be about 16% higher as compared to long chain triglycerides. With this in mind, the calculated mean net caloric energy value for MCTs used in diets is on the order of 6.8 kcal/g. This is lower than typical LCTs. According to the publication, substituting MCTs for LCTs as the source of fat in diets show reduced weight gain and reduced fat deposition in laboratory animals and humans. This is said to be due to the lower gross energy density of an efficient utilization of energy from MCTs.

[0022] From this information, medium chain triglycerides are indicated as having dietary advantages at least from the

point of view of fat deposition. Medium chain triglycerides also are indicated by art such as this as being suitable for use in the context of human food applications. MCTs however have relatively high viscosities, making them less than satisfactory for some uses.

**[0023]** Interesterification of these MCTs according to the invention includes charging them to an interesterification location or vessel as part of the charge for forming the structured lipid. Broadly, MCTs can comprise between about 15 and about 75 weight percent of the total structured lipid charge components. Typically, MCTs comprise between about 25 and about 75 weight percent of the structured lipid charge. Generally, the charged quantities of interesterification reactants correspond closely to the respective weight percents in the interesterified structured lipid. Preferably, the quantity of MCTs is between about 30 at about 60 weight percent, most preferably between about 35 and about 55 weight percent.

**[0024]** Also part of the charge for forming the structured lipids are so-called domestic oils. Domestic oils for the interesterification according to the invention include soybean oil, corn oil, cottonseed oil, canola oil, safflower oil, sunflower oil, peanut oil, olive oil, oil from grain plants, and identity preserved oils such as identity preserved canola oil and the like. Whichever edible oil is chosen, it will be a liquid oil. Hydrogenation typically need not be carried out. Oils of these types are well recognized as so-called long chain lipids. Chain lengths of these oils generally lie between C16 and C22, as will be generally appreciated in the art.

**[0025]** The charge of such domestic oil to the interesterification location or vessel broadly can be between about 15 and about 85 weight percent of the charge into the interesterification reaction vessel. Typically, the oil

comprises between about 25 and about 75 weight percent of the charge, and substantially the same level of long chain component is in the interesterified structured lipid. Preferably, this amount is between about 40 and about 70 weight percent, most preferably between about 45 and about 65 weight percent, based upon the weight of the charge or interesterified structured lipid.

**[0026]** With further reference to the domestic oils having chain lengths longer than the MCT reactant, advantageously they are preferably substantially unsaturated oils such as soybean, corn, cottonseed and canola, which are well known in the art as liquid oil commodities. Certain specialty oils also are encompassed within the preferred domestic oils. These include identity preserved canola oils and refined, bleached and deodorized high stable oils. Included is naturally high stable canola oil such as NATREON oil (trademark, available from Dow Agro Sciences, Canbra Foods), which is naturally higher in monounsaturated fats and in oleic fatty acid and lower in linolenic fatty acid. In this regard, Sornyk et al U.S. Patent No. 5,965,755 and Lanuza et al. U.S. Patent No. 6,169,190 are noted and incorporated by reference.

**[0027]** The chemical interesterification used in making the structured lipids of the compositions of the invention involves charging the reactants into an interesterification reactor vessel. Such vessels have means for heating the reactants during agitation and under reduced pressure or vacuum conditions. The reaction is carried out in the presence of a suitable interesterification catalyst and typically proceeds rapidly to completion or substantial completion. Typically, the interesterification is a reaction to or toward complete randomization, which would equate to a degree of interesterification of 100% of the fatty acyl chains.

[0028] Interestification catalysts include metal alkoxides, alkali metals, alkali metal alloys, and metal hydroxides. Alkoxides include alkali metal alkoxides, such as sodium methoxide, sodium ethoxide, potassium methoxide and potassium ethoxide. Alkali metals include sodium. Alkali metal alloys include sodium/potassium alloy, and metal hydroxides include alkali metal hydroxides such as sodium hydroxide and potassium hydroxide.

[0029] Once the interestification has proceeded to form the desired structured lipid, steps can be taken to modify the conditions away from reaction conditions. This can include inactivating the catalyst, reducing the temperature, reducing the vacuum applied, ceasing agitation, or any combination of these changes. Means for accomplishing these changes will be appreciated by those skilled in the art.

[0030] Reaction temperatures range between about 80°C and about 100°C (about 160°F to about 212°F). A most suitable temperature at which to carry out the interestification within the reaction vessel is approximately midway within this range. Vacuum conditions within the vessel range between about 5 mbar and about 100 mbar (between about 4 mm Hg and about 75 mm Hg). Preferably, the level is within the lower portion of this range, or less than about 40 mbar (about 30 mm Hg), most preferably at or below about 26.7 mbar (about 20 mm Hg).

[0031] Reaction time will range between about 30 minutes and about 2 hours. An especially suitable reaction time is about 45 minutes. This reaction time can be controlled, for example, by timed neutralization of the catalyst. Neutralization for a catalyst such as sodium methoxide can be accomplished with 0.7 weight percent of citric acid solution of 42% strength.

[0032] The interestified structured lipid can be treated to remove any residual soaps and/or to remove all the color



bodies if needed. These include filter aids and silica sources such as TRISYL® S-615 (trademark, available from W. R. Grace & Co.) used for the refining of vegetable oil. Color removal can be with a bleaching earth or the like. The structured lipid also typically will be subjected to deodorization in accordance with approaches generally known in the art.

**[0033]** In preparing the products according to the invention, the interesterified structured lipid is combined with one or more phytosterol esters to form a composition which can be used directly as an edible oil product, or also be combined with other components to make up the desired final product, as will be generally appreciated by those skilled in the art. For example, this can include combining the composition with other food components in recipes for consumable foods and the like.

**[0034]** Compositions according to the invention include the structured lipid at levels between about 90 and about 96 weight percent, based upon the total weight of the product. Typically the structured lipid will be present at between about 92 and about 94 weight percent. The phytosterol component will be included at levels between about 4 and about 10 weight percent, based on the total weight of the composition. Typically the phytosterol will be present at between about 6 and about 8 weight percent.

**[0035]** With further reference to the phytosterols that serve as the basis for the phytosterol ester components that are combined with interesterified structured lipid according to the invention, specific details concerning phytosterols can be found in U.S. Patents No. 6,117,475, No. 6,139,897, No. 6,277,431, US Patent Application Publications No. 2002/0031595 and No. 2002/0045000, and International Publications No. WO 01/13733, No. WO 01/32029 and No. WO 01/91587. Specific details concerning phytosterol esters and microparticles of phytosterol esters are found in U.S. Patent No. 6,087,353 and

U.S. Patent Application Publication No. 2002/0048606. As noted previously, each of these patents and patent publications is incorporated by reference hereinto.

[0036] The term "phytosterols" when referring to the components used in the compositions according to the present invention encompass phytosterols and/or phytostanols or derivatives of these types of compounds. It is recognized that the presence of the sterol component is useful in lowering serum cholesterol and serum triglyceride levels, as well as enhancing overall dietary efficacy. It is generally accepted, but not with certainty, that this can be explained by similarities between their respective chemical structures. By this explanation, the phytosterol displaces cholesterol from the micellar phase, thereby reducing cholesterol absorption and/or competing with receptor and/or carrier sites in the cholesterol absorption process.

[0037] Examples of compounds which fall within a meaning of "phytosterol" include sitosterol, campesterol, stigmasterol, brassicasterol, demosterol, chalinosterol, poriferasterol, coioanasterol, and natural or synthesized forms or derivatives, including isomers. Also included are compounds identified by the term phytostanol, including saturated or hydrogenated phytosterols and all natural or synthesized forms and derivatives, including the isomers. It will be appreciated that these components can be modified, such as adding side chains and also fall within the perview of the term phytosterol.

[0038] Phytosterols are typically attained from natural sources, most typically from the processing of plant oils or marine oils. Sources include vegetable oils and fish oils, vegetable oils include corn oil, wheat germ oil, soy extract, rice extract, rice bran, canola oil and sesame oil. Other sources can include tall oil pitch or soap such as those which are byproducts of the forestry industry.

[0039] Phytosterol esters are available from public sources, including from Forbes Medi-Tech, Inc. An example is PHYTROL®, a registered trademark of Forbes Medi-Tech, Inc. Compositions are sold under this brand name as cholesterol lowering agents. A typical such composition is composed of plant sterols and stanols having 14.5% campesterol, 2.4% campostanol, 50.9% beta-sitosterol, and 18.9% sitostanol. The PHYTROL® product is a fine crystalline waxy powder. Its particle size characteristic is such that greater than 80% of the particles pass through a 0.8 mm sieve and greater than 98% of the particles pass through a 2.0 mm sieve. PHYTROL® phytosterol compositions comprise from 38 to 79 weight percent sitosterol, based on the total weight of the anhydrous composition, 4 to 25 weight percent of campesterol, 6 to 18 weight percent sitostanol, and 0 to 14 weight percent campostanol. At least 97 weight percent of the components are in the form of a sterolester, and no more than 3 weight percent are free sterols. An exemplary sterolester in this regard is a phyto-S-sterol-10 ester. Such has a softening point of between 15°C and 30°C and is substantially insoluble in water at 25°C. Such a sterolester is liquid above 40°C.

[0040] With more particular reference to the phytosterol ester component, it is preferred that the quantity of stanol structures included in this component be minimized. The stanol structure is associated with hydrogenization is associated with trans-isomer structures, which have been the subject of negative health concerns. In addition, excessive hydrogenization detrimentally affects clarity of the compositions. Typically, the stanol or phytostanol content in the phytosterol ester components according to the invention will be no greater than about 20 weight percent, based upon the total weight of the phytosterol ester component. Preferably, the amount of stanol or phytostanol compounds

within the phytosterol ester component is not greater than about 15 weight percent.

**[0041]** In proceeding with a method for making the compositions according to the invention, between about 88 and about 98 weight percent of the interesterified structured lipid described herein is blended with between about 2 and about 12 percent of a phytosterol ester component, both based upon the total weight of the composition. Typically, the interesterified structured lipid is at between about 90 and about 96 weight percent, and the phytosterol ester is at between about 4 and about 10 weight percent. In a preferred arrangement, the structured lipid is prepared by an interesterification reaction as discussed herein of approximately equal weight percentages of a medium chain triglyceride and of a long chain domestic oil, each as generally discussed herein.

**[0042]** These compositions then are formulated into food products so that adequate levels of phytosterols are delivered into the body in order to reduce total cholesterol adsorption. In addition, the MCT structure fosters their oil metabolism through the hepatic system rather than through the lymphatic system, leading to reduced adipose tissue deposition for these oil products when compared with products incorporating similar quantities of other oils. The compositions also are intended to increase components of energy expenditure and substrate oxidation.

**[0043]** This structured lipid combined with phytosterol esters as discussed herein provide an excellent composition for edible oil products having good clarity, physical properties for such uses, and low trans-isomer levels. This composition provides a healthy oil that delivers salad oil, pan frying and baking functionality while serving as an adjunct to lower LDL cholesterol levels and minimizing adipose tissue deposition.

[0044] Administration of the structured lipid-based, phytosterol ester-containing oil composition according to the invention can be made at advantageous levels when included within a monitored diet. Administration doses should be at least about 0.4 grams of the oil composition per kilogram of body weight per day. A typical range is between about 0.8 and about 1 gram of this oil per kilogram of body weight per day. In an exemplary monitored diet, 40% of the total energy (approximated by calories) in the diet originate from fat, 45% of the energy from carbohydrates, and 15% of the energy from protein sources. Of the fat source, 70% can be provided by the structured lipid composition. Thus, a monitored diet designed for lowering LDL cholesterol, raising HDL cholesterol and/or raising the HDL/LDL cholesterol level in this example achieves 28% of its energy from the structured lipid-based, phytosterol ester-containing compositions according to the invention.

[0045] On a body mass basis, this type of monitored diet expends energy sources at a rate of between about 2200 and about 2500 calories per day. The structured lipid-based, phytosterol ester-containing oil compositions according to the invention exhibit 8.4 kilocalories per gram of fat, whereas a typical edible oil such as refined, bleached and deodorized canola oil exhibits 9 kilocalories per gram of fat.

[0046] Examples now are provided in order to illustrate the concepts of the invention with a certain degree of specificity. Brookfield viscosity measurements referenced herein are measured at 20°C with a No. 4 spindle at 50 rpm on a Brookfield Viscometer.

#### EXAMPLE 1

[0047] A batch reaction was carried out within a reactor vessel having heating means, agitation means and pressure reduction capabilities. The reactant charge was 50% by weight

of a medium chain triglyceride (NEOBEE® 1053) and 50% by weight of identity preserved canola oil. A sodium methoxide catalyst (95% pure) was added at 0.15 percent by weight of the edible oil reactant charge. The interesterification reaction was allowed to proceed for 45 minutes at a temperature of 90°C and a pressure of 25.3 mbar (19 mm Hg). At the end of the reaction time, neutralization was carried out with 0.7% by weight of citric acid solution of 42% strength by weight.

[0048] The thus-formed interesterified structured lipid was treated with 1% by weight TRISYL® S-615 plus 1% by weight of a filter aid. Mixing proceeded for about 8 minutes at 90-94°C, followed by filtration. This was observed to have removed all of the soap residue. The structured lipid also was bleached with 0.5% of bleaching earth and 0.5% of a filter aid in order to ensure that all color bodies were removed.

[0049] Deodorization was carried out as follows. The structured lipid was subjected to a temperature of about 230°C under a vacuum of 2.66 mbar (2 mm Hg). Steam was introduced at the rate of 0.4 volume percent of steam per hour. Deodorization treatment time was four hours.

[0050] The structured lipid was analyzed and found to have the following characteristics. No soap was detected. The smoke point was 210°C (410°F). The viscosity was measured with a Brookfield viscometer at 20°C, using the No. 4 spindle at 50 rpm. The viscosity reading for this structured lipid was 22 centipoise. The same MCT and identity preserved canola oil in the same proportions were made up into a physical blend. The Brookfield viscosity at 20°C, with spindle No. 4 at 50 rpm, was 40 centipoise, and the smoke point was 154.4°C (310°F). The canola oil, prior to blending, had a viscosity of 68 centipoise measured in the same manner.

[0051] Good product stability was indicated by a free fatty acids value of 0.03. The peroxide value (PV) was 0.2. The oxidative stability index (OSI) was 15.5 hours at 110°C. The

solids fat content (SFC) at 10°C was 0.32, indicating that the structured lipid was liquid at this temperature. The Anisidine Value (AV) was comfortably low, at 0.85. The color measurement according to PFX880 5¼ was 7.5Y/1.3R.

[0052] The peroxide value (PV) is determined in accordance with method No. Cd8-53 from the publication *Official Methods and Recommended Practices of the AOCS*, Fifth Edition (2002). Also found in this publication are method No. Ca5a-40 for free fatty acid (FFA) determination, method No. Cd18-90 for Anisidine Value (AV) determination, and method No. Cd12b-92 for Oxidative Stability Index (OSI) determination.

[0053] Various food products were prepared using the structured lipid phytosterol composition of this Example and also using control oil sources. Comparative analyses and sensory tests were conducted. The results indicate that there were no significant differences between food products prepared with the structured lipid of this Example when compared with the control oil. In some instances noted herein, the structured lipid composition according to this Example gave results that were more favorable to a statistically significant degree.

[0054] Provided in Table I are oil quality attributes which are the results of tests reporting basic quality attributes of the refined, bleached and deodorized canola oil and of the structured lipid phytosterol ester composition according to this Example.

**TABLE I**

<b>Analytical Test</b>	<b>RBD Canola Oil</b>	<b>Structured Lipid-Based Oil</b>
OSI	6-7 hrs.	16.0 hrs.
Smoke Pt.	475°F	410°F
Color – (5 ¼ )	7.0Y/0.7R	7.5Y/1.3R
FFA (%)	0.03	0.03
PV(meq/kg)	0.8	0.8
Iodine Value	100-115	55-60

Viscosity	68cp	22cp
% Trans	0.36%	0.36%
Sterol Ester	0.81%	6.00%
Campsterol	269 mg/100g	404mg/100g
Stigmasterol	14.3 mg/100g	57.3mg/100g
Beta Sitisterol	528.0 mg 100g	2992.5mg/100g

**[0055]** These data of Table I provide certain information of interest. The oxidative stability index (OSI) for the canola oil was only 6-7 hours, whereas that for the structured lipid composition of this Example was 16 hours. The higher OSI value indicates that the structured lipid-based phytosterol-containing oil remains stable and clear for a greater number of hours than the control oil. This indicates a longer shelf stability than the control oil. While the smoke point of the structured lipid of this Example is lower than that of the control canola oil, the level of 410°F (210°C) is acceptable for pan frying applications other than deep frying. In addition, this smoke point is higher than the smoke point of a composition according to this Example but which is a blend and does not subject the lipid components to interesterification.

**[0056]** The iodine value (IV) is significantly lower for the structured lipid-based oil than for the canola oil control. The IV indicates degree of unsaturation, even though the structured lipid oil based composition is liquid at room temperature. This and other physical properties indicate that the structured lipid-based composition is liquid, and there is no significant precipitation, including if stored under refrigerated temperatures for reasonable lengths of time. Crystallization will be resisted for a much longer time, under refrigeration, than for the canola oil control. The oil remains a clear liquid for a longer time than oils having quality attributes along the lines of the canola oil in Table I.



[0057] The viscosity data indicate a substantially lower viscosity for the structured lipid-based phytosterol-containing oil, indicating that this oil is lighter in weight or consistency than is the canola oil. The percent of trans-isomer is the same for the structured lipid oil as it is for canola oil. The level of 0.36% generally corresponds to the natural level of trans-isomers within canola oil and indicates that the structured lipid-based oil also enjoys this advantageously low trans-isomer percentage. The substantially higher quantity of sterol ester in the structured lipid-based oil is consistent with the phytosterol added thereto. The 0.81% sterol ester in the canola oil control represents the natural level within the canola oil.

[0058] Table I also shows levels of the major phytosterols present in each of the structured lipid-based oil and in the canola oil. It is noted that the beta-sitosterol content which is present in a 5-fold greater amount in the structured lipid-based oil over the canola oil is the most important phytosterol for LDL reduction which is found in these types of phytosterol components.

#### Shelf Life Study

[0059] The structured lipid-based phytosterol-containing oil composition of this Example 1 was subjected to a shelf life study at three different temperatures. Data were generated and are reported in Table II. The ambient storage temperature was within an open room having typical heating, ventilation and air conditioning cycles averaging on the order of 70°F (about 21°C). The 70°F (21°C) and 100°F (37.8°C) storage temperatures were within closed spaces with closely monitored temperatures. The storage temperature of 100°F is considered to be an accelerated test for shelf storage evaluation.

TABLE II

Storage Time	Storage Temp.	Peroxide Value (Meq/Kg)	Free Fatty Acids (wt. %)	Anisidine Value	OSL (hours)
Time Zero	-	0.2	0.07	1.28	16
1 Month	Ambient	0.2	0.07	0.64	15
	70°F	0.2	0.07	0.67	14
	100°F	1.8	0.07	0.69	14
3 Months	Ambient	1.2	0.07	0.64	14
	70°F	1.2	0.07	0.66	14
	100°F	3.0	0.08	1.35	12
6 Months	Ambient	3.6	0.07	0.87	12
	70°F	3.9	0.07	0.94	12
	100°F	4.3	0.08	1.85	11
7 Months	Ambient	4.0	0.07	0.74	12
	70°F	4.4	0.07	1.05	13
	100°F	4.2	0.08	2.01	12

[0060] The structured lipid oil was blended with PHYTROL® phytosterol at a ratio of 93% structured lipid and 7% phytosterol. The Table II data show a very consistent free fatty acid (FFA) weight percent. This lower free fatty acid content indicates that the structured lipid-based phytosterol-containing composition has not broken down over the seven month period, indicating that the triglycerides are intact. An anisidine value (AV) of about 2 or lower, or even 3 or lower, indicates very low beta oxidation or secondary oxidation. When the AV exceeds 3, this is an indication that the oil is beginning to become oxidized and free fatty acids have formed, which can eventually move toward rancidity.

[0061] The peroxide value (PV) is an alternative manner of judging shelf life. Bottled edible oils are generally appreciated as having acceptable shelf properties when the PV is no greater than or equal to about 8 meq/kg.

[0062] The oxidative stability index (OSI) shows that the advantageous 16 hour value for the fresh structured lipid-based oil, while reduced somewhat after seven months, is nevertheless still approximately twice that of the fresh canola oil (see Table I).

#### Comparative Sensory Testing

[0063] Comparative testing of food products incorporating the structured lipid phytosterol ester composition of this Example 1 shows the suitability of using such compositions in products which will successfully deliver the phytosterols (in greater quantities as noted in Example 15) without detracting from the sensory attributes of the food products.

#### Cake Evaluation Study

[0064] Identical cake batters were prepared with the exception of the oil component. NUTRA-CLEAR OIL® canola-based oil, available from Bunge Foods, was the control oil in this cake evaluation study. In this study, as well as in all of the other studies of this Example, a so-called "healthy oil" was used. This is the structured lipid-based, phytosterol ester-containing edible oil composition of this Example. In making up the respective yellow cake batters and baked cakes, subjective and objective test results show no significant differences. More specifically, for each of the control and healthy oils, the respective values were 0.909 and 0.918 for specific gravity, 10,260 and 10,180 centipoise for the viscosity of the batter, 68°F (20°C) batter temperature for both, smooth batter appearance for both, cake volume of 1235cc for both, firm texture for both, with a "moist" comment regarding performance for the control and a "gummy" performance comment for the healthy oil. The moisture contents for the control oil and healthy oil were 41.21% and

41.86%, respectively, and the water activities were 0.927 and 0.942; respectively.

[0065] A sample of each baked cake was subjected to analyzation within a TA-XT2 Texture Analyzer manufactured by Stable Micro Systems, of Goldalming, Surrey, England. This analyzer was set at the following parameters used to analyze the yellow cakes for texture: 3.00 mm/s pretest speed, 1.70 mm/s test speed, 1.70 mm/s post-test speed, 1.0% rupture test distance, 70% distance, 100 grams force, a time of 3.00 seconds, a count of 5, and a 25kg load cell. The control analyzed at 2919.57 grams of force, and the healthy oil analyzed at 2741.46 grams of force. This is a measure of the grams of force required to depress the cake sample at a given rate as set on the Texture Analyzer. These objectively measured values of texture gave the conclusion of no significant difference between the cakes made with the two different types of oils.

[0066] In addition, these yellow cakes were subjected to sensory evaluation according to the triangle technique as specified in *Sensory Evaluation Techniques*, 3<sup>rd</sup> Edition, CRC Press, page 369 (1999). A panel of 40 individuals was presented with yellow cake samples in a blind taste test. Two of the samples were either the control cake or the healthy oil cake, with the third sample being of the other cake. Each participant was requested to select the sample which was different from the other two in sensory attributes. 18 out of the 40 participants correctly identified the different cake sample, which indicates no significant sensory difference between the two cakes according to these triangle sensory test results of the control oil containing cake and of the healthy oil containing cake. This is at a 95% confidence level.

#### Muffin Evaluation Study

[0067] Muffins were prepared using consumer-type muffin mixes that require oil in the make-up instructions. In one test batter, the NUTRA CLEAR OIL® canola oil product was used as the control, and the structured lipid phytosterol ester composition of this Example was the so-called healthy oil. The respective values of the control oil to the healthy oil were as follows: specific gravity, 0.943 and 0.952; viscosity 22,040 cps and 20,800 cps; moisture 35.70% and 39.80%; and water activity 0.943 and 0.952, respectively. In each case, the batter temperature was 68°F (20°C) and the batter appearance was smooth. Each was judged to have good texture and was moist. Informal sensory evaluations indicated no flavor differences, although an appearance difference was noted in that the control muffins had a peaked appearance, rather than a rounded top appearance of the healthy oil muffins. Overall, no significant differences were found between the two muffin products.

#### Waffle Evaluation Study

[0068] Waffles were made using BUNGE® pancake mix having a specified amount of oil added to the batter to produce Belgian style waffles. Both the control oil and the healthy oil produced similar waffles. There were no differences in batter viscosity or specific gravity. Informal sensory evaluations showed no appearance or flavor differences. Each had a nice golden brown color and a clean flavor.

#### Sautéed Vegetable Evaluation Study

[0069] In this study, the control canola based oil product and the healthy oil product were evaluated, as was a third oil, namely Bertolli olive oil as sold to retail consumers. Vegetables were stir fried in each oil and evaluated for

flavor, color and functionality attributes. The healthy oil exhibited some smoking and foaming. Sensory evaluations showed no differences in appearance. It was noted that the vegetables sautéed in the healthy oil exhibited a "cleaner" flavor than the other oils, which enhanced the flavors of the vegetables.

#### Pan-Fried Chicken Evaluation Study

[0070] Long chicken strips were placed into a tempura-type batter and fried in the control canola oil and the healthy oil. As with the vegetable evaluation, some smoking and foaming was observed when pan frying in the healthy oil. Informal sensory evaluations showed no differences in appearance. Taste testing showed that a "fishy" taste was noted in the samples fried in the control oil, which taste was considered objectionable. The chicken fried in the healthy oil was very desirable with a very "clean" flavor and no aftertaste.

#### Salad Dressing Evaluation Study

[0071] Vinegar and oil salad dressings were prepared using a 3:1 ratio of 3 parts oil to 1 part red wine vinegar. One sample used the NUTRA-CLEAR OIL® canola oil, and the other used the healthy oil composition of this Example. Both oils produced dressings which were very similar in appearance. Sensory evaluations showed that the canola oil dressing seemed bland, while the healthy oil dressing seemed to have more bitter vinegar flavor, which is judged to be a positive flavor attribute.

[0072] A triangle sensory test was conducted in substantially the same manner as the yellow cake triangle sensory testing reported above. 15 of 33 respondents correctly discerned which salad dressing was different. This indicates that there was no significant difference in sensory

attributes between the two salad dressings, at a 95% confidence level.

#### Olive Oil Salad Dressing Evaluation

[0073] Salad dressings were made up as in the salad dressing evaluation study above. In this instance, the control oil was extra virgin olive oil rather than canola oil. A salad dressing made from the olive oil was subjected to sensory evaluation in comparison with a salad dressing made from the healthy oil. 82% of the panelists indicated that they preferred the healthy oil salad dressing to the extra virgin olive oil salad dressing. This is a statistically significant difference at a very high level of confidence.

#### Chicken Frying Evaluation

[0074] Chicken pieces were fried in either extra virgin olive oil or in the healthy oil of this Example. 39 participants tasted the fried chicken and rated same on a scale of 1 through 5, with 1 indicating extreme liking and 5 indicating extreme disliking. The panel of participants rated the fried chicken in eight categories. In six of the categories, there was no statistical difference between chicken cooked in the two oils. In two of the categories, flavor acceptability and aftertaste, the chicken fried in the healthy oil was statistically better in terms of positive preference than was the chicken cooked in the extra virgin olive oil. In each of the eight sensory categories, a t-Test was performed, each being a two-sample assuming equal variances. The data are presented in Table III, which reports values with rounding at four significant figures.

**TABLE III****Overall Appearance Acceptability**

	<b>“Healthy” Oil</b>	<b>Olive Oil</b>
<b>Mean</b>	2.344	2.423
<b>Variance</b>	1.067	0.823
<b>Observations</b>	39	39
<b>Pooled Variance</b>	0.945	
<b>Hypothesized Mean Difference</b>	0	
<b>df</b>	76	
<b>t Stat</b>	-0.361	
<b>P(T&lt;=t) one-tail</b>	0.360	
<b>t Critical one-tail</b>	1.665	
<b>P(T&lt;=t) two-tail</b>	<b>0.719</b>	
<b>t Critical two-tail</b>	1.992	

**Acceptability of Color**

	<b>“Healthy” Oil</b>	<b>Olive Oil</b>
<b>Mean</b>	2.208	2.397
<b>Variance</b>	0.851	0.660
<b>Observations</b>	39	39
<b>Pooled Variance</b>	0.755	
<b>Hypothesized Mean Difference</b>	0	
<b>df</b>	76	
<b>t Stat</b>	-0.964	
<b>P(T&lt;=t) one-tail</b>	0.169	
<b>t Critical one-tail</b>	1.665	
<b>P(T&lt;=t) two-tail</b>	<b>0.338</b>	
<b>t Critical two-tail</b>	1.992	

**Flavor Acceptability**

	<b>“Healthy” Oil</b>	<b>Olive Oil</b>
<b>Mean</b>	2.357	2.808
<b>Variance</b>	0.676	1.153
<b>Observations</b>	37	39
<b>Pooled Variance</b>	0.921	
<b>Hypothesized Mean Difference</b>	0	
<b>df</b>	74	
<b>t Stat</b>	-2.048	
<b>P(T&lt;=t) one-tail</b>	0.022	
<b>t Critical one-tail</b>	1.666	
<b>P(T&lt;=t) two-tail</b>	<b>0.044</b>	
<b>t Critical two-tail</b>	1.993	



### Mouthfeel/Texture Acceptability

	<b>“Healthy” Oil</b>	<b>Olive Oil</b>
<b>Mean</b>	2.8	3.0
<b>Variance</b>	1.223	1.369
<b>Observations</b>	39	39
<b>Pooled Variance</b>	1.296	
<b>Hypothesized Mean Difference</b>	0	
<b>df</b>	76	
<b>t Stat</b>	-0.766	
<b>P(T&lt;=t) one-tail</b>	0.223	
<b>t Critical one-tail</b>	1.665	
<b>P(T&lt;=t) two-tail</b>	<b>0.446</b>	
<b>t Critical two-tail</b>	1.992	

### Eating Quality

	<b>“Healthy” Oil</b>	<b>Olive Oil</b>
<b>Mean</b>	2.770	3.113
<b>Variance</b>	1.064	1.265
<b>Observations</b>	37	38
<b>Pooled Variance</b>	1.1658	
<b>Hypothesized Mean Difference</b>	0	
<b>df</b>	73	
<b>t Stat</b>	-1.375	
<b>P(T&lt;=t) one-tail</b>	0.087	
<b>t Critical one-tail</b>	1.666	
<b>P(T&lt;=t) two-tail</b>	<b>0.173</b>	

### Acidity/Bitterness

	<b>“Healthy” Oil</b>	<b>Olive Oil</b>
<b>Mean</b>	2.605	2.974
<b>Variance</b>	0.570	0.868
<b>Observations</b>	38	39
<b>Pooled Variance</b>	0.721	
<b>Hypothesized Mean Difference</b>	0	
<b>df</b>	75	
<b>t Stat</b>	-1.907	
<b>P(T&lt;=t) one-tail</b>	0.030	
<b>t Critical one-tail</b>	1.665	
<b>P(T&lt;=t) two-tail</b>	<b>0.060</b>	
<b>t Critical two-tail</b>	1.992	

## Aftertaste

	"Healthy" Oil	Olive Oil
Mean	2.378	2.974
Variance	0.575	1.184
Observations	37	39
Pooled Variance	0.888	
Hypothesized Mean Difference	0	
df	74	
t Stat	-2.757	
P(T<=t) one-tail	0.004	
t Critical one-tail	1.666	
P(T<=t) two-tail	0.007	
t Critical two-tail	1.992	

## Overall Acceptability

	"Healthy" Oil	Olive Oil
Mean	2.603	2.936
Variance	0.923	1.318
Observations	39	39
Pooled Variance	1.121	
Hypothesized Mean Difference	0	
df	76	
t Stat	-1.390	
P(T<=t) one-tail	0.084	
t Critical one-tail	1.665	
P(T<=t) two-tail	0.168	
t Critical two-tail	1.991	

### EXAMPLE 2

[0075] A structured lipid was made substantially in accordance with Example 1. The charge was 50% identity preserved canola oil and 50% NEOBEE® 1053 MCT oil. Interesterification and deodorization proceeded. The structured lipid had a smoke point of 207°C (405°F). Further analysis showed an SFC at 10°C of 0.55, an Iodine Value of 49.5 and an OSI of 10.65 hours at 110°C. Its peroxide value was less than 0.1, and the free fatty acids were at 0.02. C8 analysis was 18.54%, and C10 analysis was 17.41%, with percent trans being 0.84%. Analyzed total saturates was 41.93%. This structured lipid is formulated into a "healthy" oil as described herein by blending same with a phytosterol ester,

the structured lipid being at 92 weight percent and the phytosterol being at 8 weight percent, based on the total weight of the healthy oil.

#### EXAMPLE 3

[0076] Chemical interesterification was carried out substantially in accordance with Example 1. The charges were 65 percent by weight of BUNGE® non-hydrogenated corn oil and 35 percent by weight of C8/C10 medium chain triglyceride. The resulting structured lipid was treated to remove soaps and subjected to deodorization. The color measurement was 8.0Y/1.0R. Analysis showed that the Brookfield viscosity was 48 centipoise at 20°C with a spindle No. 4 at 50 rpm. The smoke point was 214.5°C (418°F). This structured lipid is formulated into a "healthy" oil as described herein by blending same with a phytosterol ester, the structured lipid being at 93 weight percent and the phytosterol being at 7 weight percent, based on the total weight of the healthy oil.

#### EXAMPLE 4

[0077] Soybean oil and MCTs were charged to a reaction vessel at a ratio of 65:35 of soy:MCT. The resulting interesterified structured lipid had a viscosity of 44 centipoise at 20°C on the Brookfield viscometer with spindle No. 4 at 50 rpm. The smoke point was 213.3°C (416°F). The color measurement was 13.0Y/2.0R. When made up into a physical blend product in the same proportions, the same oil and MCT had a Brookfield viscosity at 20°C, with spindle No. 4 at 50 rpm, of 56 cps, and the smoke point was 179°C (354°F). The soybean oil, prior to blending, had a viscosity of 60 cp measured in the same manner. This structured lipid is formulated into a "healthy" oil as described herein by

blending same with a phytosterol ester, the structured lipid being at 94 weight percent and the phytosterol ester being at 6 weight percent, based on the total weight of the healthy oil.

#### EXAMPLE 5

[0078] Interesterification was carried out on a charge of 32.5 weight percent corn oil, 32.5 weight percent cottonseed oil, and 35 weight percent MCTs. The corn oil had a Brookfield viscosity of 64 cps measured as in Example 1. After proceeding substantially in accordance with Example 1, the thus prepared structured lipid had a Brookfield viscosity at 20°C, with spindle No. 4 at 50 rpm, of 48 centipoise. The smoke point was 201°C (394°F). The color measurement was 22.0Y/2.9R. When made into a physical blend product in the same proportions, these same components gave a Brookfield viscosity of 56 cp and a smoke point of 176.7°C (350°F), measured in the same manner. This structured lipid is formulated into a "healthy" oil as described herein by blending same with a phytosterol ester, the structured lipid being at 93 weight percent and the phytosterol ester being at 7 weight percent, based on the total weight of the healthy oil.

#### EXAMPLE 6

[0079] BUNGE® corn oil (65 weight percent) and 35 weight percent MCTs having 70% C10 were subjected to a randomizing interesterification reaction substantially in accordance with Example 1. The resulting structured lipid had a Brookfield viscosity of 48 cps, with the No. 4 spindle at 50 rpm, at 20°C. The smoke point was 199°C (390°F). The color measurement was 9.0Y/1.5R. This structured lipid is formulated into a "healthy" oil as described herein by blending same with a phytosterol ester, the structured lipid

being at 92 weight percent and the phytosterol ester being at 8 weight percent, based on the total weight of the healthy oil.

#### EXAMPLE 7

[0080] A charge into the interesterification process substantially in accordance with Example 1 was as follows: soybean oil at 40 weight percent, cottonseed oil at 25 weight percent, and MCTs at 35 weight percent. The resulting structured lipid had a Brookfield viscosity of 48 centipoise with spindle No. 4 at 50 rpm and at 20°C. The smoke point was 198°C (388°F). The color measurement was 22.0Y/3.3R. A physical blend product made of these same components in the same proportions had a Brookfield viscosity under the same conditions of 56 cp and a smoke point of 172°C (342°F). This structured lipid is formulated into a "healthy" oil as described herein by blending same with a phytosterol ester, the structured lipid being at 94 weight percent and the phytosterol ester being at 6 weight percent, based on the total weight of the healthy oil.

#### EXAMPLE 8

[0081] A charge into the interesterification process substantially in accordance with Example 1 was as follows: soybean oil at 60 weight percent, cottonseed oil at 25 weight percent, and MCTs at 15 weight percent. The resulting structured lipid had a Brookfield viscosity of 40 centipoise with spindle No. 4 at 50 rpm and at 20°C. The smoke point was 203.3°C (398°F). The color measurement was 22.Y/3.5R. A physical blend of these same components in these proportions had a Brookfield viscosity of 48 cps and a smoke point of 183°C (362°F), measured in accordance with this Example. This structured lipid is formulated into a "healthy" oil as described herein by blending same with a phytosterol ester,

the structured lipid being at 95 weight percent and the phytosterol being at 5 weight percent, based on the total weight of the healthy oil.

#### EXAMPLE 9

[0082] Soybean oil and MCTs were charged to a reaction vessel at a ratio of 75:25 of soy:MCT. The resulting interesterified structured lipid had a viscosity of 44 centipoise at 20°C on the Brookfield viscometer with spindle No. 4 at 50 rpm. The color measurement was 4.5Y/1.9R. The smoke point was 210°C (410°F). A physical blend of these components in these same proportions gave a Brookfield viscosity of 56 cps and a smoke point of 175.5°C (348°F), measured in accordance with this Example. This structured lipid is formulated into a "healthy" oil as described herein by blending same with a phytosterol ester, the structured lipid being at 92 weight percent and the phytosterol being at 8 weight percent, based on the total weight of the healthy oil.

#### EXAMPLE 10

[0083] Canola oil (Natreon identity preserved oil) and MCTs were charged to a reaction vessel at a ratio of 60:40 of oil:MCT. The resulting interesterified structured lipid had a viscosity of 44 centipoise at 20°C on the Brookfield viscometer with spindle No. 4 at 50 rpm. The smoke point was 197.8°C (388°F). A physical blend product of these components at these proportions had a Brookfield viscosity of 48 cps and a smoke point of 187.8° (370°F), measured according to this Example. This structured lipid is formulated into a "healthy" oil as described herein by blending same with a phytosterol ester, the structured lipid being at 92 weight percent and the phytosterol components being at 8 weight percent, based on the total weight of the healthy oil.

#### EXAMPLE 11

[0084] Interesterification was carried out on a charge of 70 weight percent canola oil (Natreon oil) and 30 weight percent MCTs. After proceeding substantially in accordance with Example 1, the thus prepared structured lipid had a Brookfield viscosity at 20°C, with spindle No. 4 at 50 rpm, of 48 centipoise. The smoke point was 202°C (396°F). A same-proportion physical blend product of these had a Brookfield viscosity of 52 cps and a smoke point of 182.2°C (360°F) measured according to this Example. This structured lipid is formulated into a "healthy" oil as described herein by blending same with a phytosterol ester, the structured lipid being at 92 weight percent and the phytosterol being at 8 weight percent, based on the total weight of the healthy oil.

#### EXAMPLE 12

[0085] BUNGE® corn oil (70 weight percent) and 30 weight percent MCTs were subjected to a randomizing interesterification reaction substantially in accordance with Example 1. The resulting structured lipid had a Brookfield viscosity of 48 cps, with the No. 4 spindle at 50 rpm, at 20°C. The smoke point was 214.4°C (418°F). A same-proportion physical blend of these had a Brookfield viscosity of 48 cps and a smoke point of 180°C (356°F) measured according to this Example. This structured lipid is formulated into a "healthy" oil as described herein by blending same with a phytosterol ester, the structured lipid being at 92 weight percent and the phytosterol ester being at 8 weight percent, based on the total weight of the healthy oil.

#### EXAMPLE 13

[0086] A charge into the interesterification process substantially in accordance with Example 1 was as follows: canola oil at 60 weight percent and MCTs at 40 weight percent.

The resulting structured lipid had a Brookfield viscosity of 40 centipoise with spindle No. 4 at 50 rpm and at 20°C. The smoke point was 194.4°C (382°F). A physical blend of these components in the same proportion, when tested according to this Example, gave a Brookfield viscosity of 44 cps and a smoke point of 175.5°C (348°F). Canola oil, before blending or reaction, had a viscosity of 64 cps, measured in the same manner. This structured lipid is formulated into a "healthy" oil as described herein by blending same with a phytosterol ester, the structured lipid being at 92 weight percent and the phytosterol ester being at 8 weight percent, based on the total weight of the healthy oil.

#### EXAMPLE 14

[0087] A charge into the interesterification process substantially in accordance with Example 1 was as follows: canola oil at 70 weight percent and MCTs at 30 weight percent. The resulting structured lipid had a Brookfield viscosity of 40 centipoise with spindle No. 4 at 50 rpm and at 20°C. The smoke point was 212.2°C (414°F). A physical blend of these reactants in the same proportion, when tested according to this Example, gave a Brookfield viscosity of 48 cps and a smoke point of 180°C (356°F). This structured lipid is formulated into a "healthy" oil as described herein by blending same with a phytosterol ester, the structured lipid being at 93 weight percent and the phytosterol being at 7 weight percent, based on the total weight of the healthy oil.

#### EXAMPLE 15

[0088] The structured lipid-based phytosterol-containing composition of Example 1 was evaluated in multiple food applications. The following illustrates the levels at which cholesterol adsorption can be reduced with this composition when compared with a commercial edible oil. St-Onge et al.,



"Phytosterols and Human Lipid Metabolism: Efficacy, Safety and Novel Foods," *Lipids*, Volume 38, No. 4 (2003) indicates that intakes of 150 and 300 mg of phytosterols added to sterol-free edible oil can reduce total cholesterol adsorption by 12.1% and 27.9%, respectively. Recommended daily allowances of vegetables according to 21 C.F.R. 101.12 are 110 grams of vegetables. When a phytosterol ester component was added to refined, bleached and deodorized canola oil (control oil) and used to stirfry vegetables, 90 mg of phytosterol component were found to be within the 110 grams of vegetables. When the structured lipid phytosterol ester composition of this Example was substituted for the canola oil, 410 mg of phytosterol component were found to be within the 110 grams of vegetables. This represents a phytosterol delivery enhancement of over 4.5 times.

**[0089]** For chicken, the recommended amount according to the 21 C.F.R. 101.12 reference is 55 grams of chicken. When 55 grams of chicken were pan fried with the canola oil control, 30 mg of phytosterol component were found in the chicken, whereas when the structured lipid phytosterol ester oil was used, 200 mg of phytosterol component were on or in the chicken. The chicken that was pan fried in the structured lipid oil contained over 6.6 times of the phytosterol delivered when the control oil was used.

**[0090]** Muffins also have a 21 C.F.R. 101.12 daily value reference amount of 55 grams. When blueberry muffins were baked with the control canola oil as the oil component of the batter, 30 mg of phytosterol component were found within the baked muffin. When the structured lipid phytosterol ester oil was used, 160 mg of phytosterol component were included within the 55 grams of muffin. The structured lipid oil composition resulted in delivery of over 5.3 percent more sterol than the control oil when the control oil was used in the muffin batter.

[0091] The 21 C.F.R. 101.12 reference amount for cake is 80 grams. When cake was baked from a yellow cake batter including the control canola oil, the amount of sterol ester was 50 mg per 80 grams of yellow cake. When the structured lipid phytosterol ester oil was used in the yellow cake batter, 300 mg of sterol esters were delivered per 80 grams of yellow cake. This represents a 6-fold increase in sterol ester delivery when using the structured lipid.

[0092] A waffle has a daily value reference amount according to 21 C.F.R. 101.12 of 85 grams. When the control canola oil was used in a waffle batter baked into waffles, the amount of sterol esters found within the waffles was 10 mg per 85 grams of waffle. When the structured lipid phytosterol ester was used instead of the control oil, 70 mg of sterol esters were delivered into the baked waffle per 85 grams of waffle. This represented a 7-fold increase in sterol delivery by utilizing the structured lipid sterol composition of this Example.

[0093] It will be understood that the embodiments of the present invention which have been described are illustrative of some of the applications of the principles of the present invention. Numerous modifications may be made by those skilled in the art without departing from the true spirit and scope of the invention.

## CLAIMS

1. An oil composition, comprising:

at least about 88 weight percent, based on the total weight of the oil composition, of an interesterified structured lipid component;

said structured lipid component is a reaction product of an interesterification reactant charge, said reactant charge having between about 15 and about 75 weight percent, based upon the total weight of the charge, of a medium chain triglyceride having fatty acid chains from C6 to C12 in length, reacted with between about 15 and about 85 weight percent, based upon the total weight of the charge, of a long chain domestic oil having fatty acid chains of at least C16 in length; and

up to about 12 weight percent, based on the total weight of the oil composition, of a phytosterol ester component.

2. The composition in accordance with claim 1, wherein said structured lipid component comprises at least about 90 weight percent of the oil composition, and said phytosterol ester component comprises up to about 10 weight percent of the oil composition, both based upon the total weight of the oil composition.

3. The composition in accordance with claim 1, wherein said structured lipid component comprises at least about 92 weight percent of the oil composition, based upon the total weight of the oil composition.

4. The composition in accordance with claim 1, wherein said structured lipid component comprises up to about 96 weight percent of the oil composition, based upon the total weight of the oil composition.

5. The composition in accordance with claim 1, wherein said structured lipid component comprises between about 92 and about 94 weight percent of the oil composition, based upon the total weight of the oil composition.

6. The composition in accordance with claim 1, wherein said medium chain triglyceride amount is between about 25 and about 75 weight percent of the interesterification charge, and the amount of the domestic oil is between about 25 and about 75 weight percent of the charge.

7. The composition in accordance with claim 1, wherein said medium chain triglyceride amount is between about 30 and about 60 weight percent of the interesterification charge, and the amount of the domestic oil is between about 40 and about 70 weight percent of the charge.

8. The composition in accordance with claim 1, wherein said medium chain triglyceride amount is between about 35 and about 55 weight percent of the interesterification charge, and the amount of the domestic oil is between about 45 and about 65 weight percent of the charge.

9. The composition in accordance with claim 1, wherein said structured lipid component has a Brookfield viscosity at 20°C of between about 20 and about 52 centipoise.

10. The composition in accordance with claim 1, wherein said structured lipid component has a smoke point of at least about 195°C (at least about 383°F).

11. The composition in accordance with claim 1, wherein said structured lipid component has a smoke point of at least about 205°C (greater than about 400°F).

12. The composition in accordance with claim 1, wherein said phytosterol ester component has no greater than about 20% by weight, based upon the total weight of the phytosterol ester component, of a phytostanol.

13. The composition in accordance with claim 1, wherein said oil composition reduces total cholesterol adsorption in individuals.

14. The composition in accordance with claim 1, further including an edible carrier component administered to an individual at a level of at least about 0.4 grams of said oil composition per kilogram of body weight per day.

15. The composition in accordance with claim 1, wherein said oil composition is a clear liquid and remains a clear liquid for at least about six months of storage at about 21°C.

16. The composition in accordance with claim 1, wherein said oil composition has sensory attributes which are not significantly different from, or are significantly superior to, corresponding sensory properties of canola oils which do not have a phytosterol component.

17. The composition in accordance with claim 1, wherein said oil composition has sensory attributes which are not significantly different from, or are significantly superior to, corresponding sensory properties of olive oils which do not have a phytosterol component.

18. The composition in accordance with claim 1, wherein said medium chain triglyceride is selected from the group consisting of caprylic triglyceride, capric triglyceride, and combinations thereof.

19. The composition in accordance with claim 1, wherein said domestic oil is selected from the group consisting of soybean oil, corn oil, cottonseed oil, canola oil, olive oil, peanut oil, safflower oil, sunflower oil, oil from grain plants, and combinations thereof.

20. An oil composition, comprising:

an interesterified structured lipid component which is a reaction product of an interesterification reactant charge, said reactant charge having between about 15 and about 85 weight percent, based upon the total weight of the charge, of a medium chain triglyceride having fatty acid chains from C6 to C12 in length, reacted with between about 15 and about 85 weight percent, based upon the total weight of the charge, of a long chain domestic oil having fatty acid chains of at least C16 in length;

a phytosterol ester component; and

said structured lipid component and said phytosterol ester component provide an oil composition which has a Brookfield viscosity at 20°C of between about 20 and about 52 centipoise.

21. The composition in accordance with claim 20, wherein said structured lipid component comprises at least about 88 weight percent of the oil composition, based upon the total weight of the oil composition.

22. The composition in accordance with claim 20, wherein said structured lipid component comprises up to about 98 weight

percent of the oil composition, based upon the total weight of the oil composition.

23. The composition in accordance with claim 20, wherein said structured lipid component of the composition comprises between about 90 and about 96 weight percent of the composition, based upon the total weight of the oil composition.

24. The composition in accordance with claim 20, wherein said structured lipid component comprises between about 92 and about 94 weight percent of the composition, based upon the total weight of the oil composition.

25. The composition in accordance with claim 20, wherein said medium chain triglyceride amount is between about 35 and about 55 weight percent of the interesterification charge, and the amount of the domestic oil is between about 45 and about 65 weight percent of the charge.

26. The composition in accordance with claim 20, wherein said structured lipid has a smoke point of at least about 195°C (at least about 383°F).

27. The composition in accordance with claim 20, wherein said structured lipid has a smoke point of at least about 205°C (greater than about 400°F).

28. The composition in accordance with claim 20, wherein said structured lipid component has a Brookfield viscosity at 20°C of between about 20 and about 52 centipoise.

29. The composition in accordance with claim 20, wherein said medium chain triglyceride amount is between about 30 and about

60 weight percent of the interesterification charge, and the amount of the domestic oil is between about 40 and about 70 weight percent of the charge.

30. The composition in accordance with claim 20, wherein said medium chain triglyceride amount is between about 35 and about 55 weight percent of the interesterification charge, and the amount of the domestic oil is between about 45 and about 65 weight percent of the charge.

31. The composition in accordance with claim 20, further including an edible carrier component administered to an individual at a level of at least about 0.4 grams of said oil composition per kilogram of body weight per day.

32. The composition in accordance with claim 20, wherein said oil composition is a clear liquid and remains a clear liquid for at least about six months of storage at about 21°C.

33. The composition in accordance with claim 20, wherein said oil composition has sensory attributes which are not significantly different from, or are significantly superior to, corresponding sensory properties of canola oils which do not have a phytosterol component.

34. The composition in accordance with claim 20, wherein said oil composition has sensory attributes which are not significantly different from, or are significantly superior to, corresponding sensory properties of olive oils which do not have a phytosterol component.

35. The composition in accordance with claim 20, wherein said medium chain triglyceride is selected from the group



consisting of caprylic triglyceride, capric triglyceride, and combinations thereof.

36. The composition in accordance with claim 20, wherein said domestic oil is selected from the group consisting of soybean oil, corn oil, cottonseed oil, canola oil, olive oil, peanut oil, safflower oil, sunflower oil, oil from grain plants, and combinations thereof.

37. A method for making a health and nutrition promoting oil composition, comprising:

- providing a medium chain triglyceride having carbon chain lengths of between C6 and C12;

- providing domestic oil having carbon chain lengths of between C16 and C22;

- introducing a reactant charge to a reaction location, the reactant charge including between about 15 and about 85 weight percent of the medium chain triacylglyceride and between about 15 and about 85 weight percent of said domestic oil, based upon the total weight of the reactant charge;

- interesterifying said reactant charge into an interesterified structured lipid component; and

- combining said interesterified structured lipid component with a phytosterol ester component to provide an oil composition which is consumable by an individual and which promotes health and nutrition of that individual, said combining being such that said the oil composition contains at least about 90 weight percent structured lipid component and up to about 10 weight percent phytosterol ester component, based on the total weight of the oil composition.

38. The method in accordance with claim 37, wherein said composition has a Brookfield viscosity at 20°C of between about 20 and about 52 centipoise.

39. The method in accordance with claim 37, wherein said pan release composition has a smoke point of at least about 195°C (at least about 383°F).

40. A method for using a medium chain triglyceride in a health and nutrition promoting composition, comprising:

providing a medium chain triglyceride having carbon chain lengths of between C6 and C12;

providing domestic oil having carbon chain lengths of between C16 and C22;

introducing a reactant charge to a reaction location, the reactant charge including between about 15 and about 85 weight percent of the medium chain triglyceride and between about 15 and about 85 weight percent of said domestic oil, based upon the total weight of the reactant charge;

interesterifying said reactant charge into an interesterified structured lipid component;

combining said interesterified structured lipid component with a phytosterol ester component to provide a health and nutrition promoting composition; and

administering the composition to an individual in order to promote the health and nutrition of that individual.

41. The method in accordance with claim 40, wherein said composition has a Brookfield viscosity at 20°C of between about 20 and about 52 centipoise.

42. The method in accordance with claim 40, wherein said composition has a smoke point of at least about 195°C (at least about 383°F).

43. The method in accordance with claim 40, comprising combining at least about 88 weight percent of the structured lipid component, based upon the total weight of the

composition, with not greater than about 12 weight percent of the phytosterol ester component.

44. The method in accordance with claim 40, comprising combining at least about 90 weight percent of the structured lipid component and up to about 10 weight percent of the phytosterol component, both based upon the total weight of the oil composition.

45. The method in accordance with claim 40, wherein said adsorption reduces LDL cholesterol adsorption by the individual.

46. The method in accordance with claim 40, wherein said administering is at a level of at least about 0.4 grams of said oil composition per kilogram of body weight of the individual.

47. The method in accordance with claim 40, wherein said oil composition is a clear liquid and remains a clear liquid for at least about six months of storage at about 21°C.

48. The method in accordance with claim 40, wherein said oil composition has sensory attributes which are not significantly different from, or are significantly superior to, corresponding sensory properties of canola oils or olive oils which do not have a phytosterol component.

Abstract of the Disclosure

STRUCTURED LIPID CONTAINING COMPOSITIONS AND METHODS  
WITH HEALTH AND NUTRITION PROMOTING CHARACTERISTICS

[0094] Medium chain triglyceride oils are interesterified with long chain domestic oils in order to form interesterified structured lipids. These structured lipids find special application in combination with phytosterols to provide compositions and methods for enhancing health and nutrition characteristics. The compositions preferably have a structured lipid content of between about 92 and about 96 weight percent and a phytosterol ester content of between about 4 and about 8 weight percent, based on the total weight of the health and nutrition promoting composition.

**COMBINED DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION**

As a below-named inventor, I hereby declare that:

My residence, post office address and citizenship is as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

**STRUCTURED LIPID CONTAINING COMPOSITIONS AND METHODS WITH  
HEALTH AND NUTRITION PROMOTING CHARACTERISTICS**

the specification of which

(check one) ☒ is attached hereto

☐ was filed on \_\_\_\_\_ as Application Serial  
No. \_\_\_\_\_ and was amended on \_\_\_\_\_ (if  
applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendments referred to above.

I acknowledge the duty to disclose information which is material to the patentability of this application in accordance with Title 37, Code of Federal Regulations, Section 1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed: NONE.

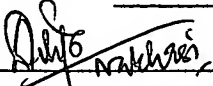
I hereby claim the benefit under Title 35, United States Code, Section 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, Section 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, Section 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application: NONE.

I hereby appoint Raymond M. Mehler, Reg. No. 26,306; Fred S. Lockwood, Reg. No. 14,772; Granger Cook, Jr., Reg. No. 18,283; Daniel C. McEachran, Reg. No. 19,804; Edward M. Keating, Reg. No. 20,646; John L. Alex, Reg. No. 22,017; Daniel M. Riess, Reg. No. 24,375; Eugene M. Cummings, Reg. No. 24,398; James S. Pristelski, Reg. No. 27,222; Gary W. McFarron, Reg. No. 27,357; Edward D. Manzo, Reg. No. 28,139; Joel H. Bock, Reg. No. 29,045; Stephen B. Heller, Reg. No. 30,181; David Lesht, Reg. No. 30,472; Andrew G. Kolomayets, Reg. No. 33,723; Mark J. Murphy, Reg. No. 34,225; Michael J. McGee, Reg. No. 43,789; David M. Mundt, Reg. No. 41,207; William H. Magidson, Reg. No. 19,902; Renee C. Barthel, Reg. No. 48,356; Panasarn Aim Jirut, Reg. No. 51,849; and Michael D. Zaronias, Reg. No. 54,564, my attorneys with full power of substitution and revocation, to prosecute this application and to transact all business in the Patent and Trademark Office in connection therewith. Address all telephone calls to Cook, Alex, McFarron, Manzo, Cummings & Mehler, Ltd. at telephone number (312) 236-8500. Address all correspondence to Cook, Alex, McFarron, Manzo, Cummings & Mehler, Ltd. 200 West Adams Street, Suite 2850, Chicago, Illinois 60606.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false

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Full name of sole or first inventor Dilip K. Nakhasi

Inventor's signature 

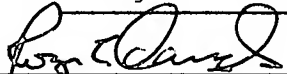
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